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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,948	05/04/2001	Samir M. Hanash	A31909-PCT USA	8499

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[REDACTED] EXAMINER

RAWLINGS, STEPHEN L

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1642

DATE MAILED: 04/09/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/848,948	HANASH ET AL.
	Examiner	Art Unit
	Stephen L. Rawlings, Ph.D.	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) 6-13 and 19-32 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-5 and 14-18 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input checked="" type="checkbox"/> Other: <i>Notice to Comply</i> .

DETAILED ACTION

1. The election with traverse filed January 21, 2003 in Paper No. 7 is acknowledged and has been entered. Applicants elected the invention of group XIV, claims 1-7 and 14-18, insofar as the claims are drawn to a method for diagnosis of cancer; additionally, Applicants elected the species of invention wherein said cancer is lung cancer.
2. Claims 1-32 are pending in the application. Claims 6-13 and 19-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention or species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
3. Claims 1-5 and 14-18 are currently subject to examination.

Election/Restrictions

4. Applicant's election with traverse in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the criteria required for proper restriction have not been met.

Applicants' arguments have been carefully considered and, if part, found persuasive. Because the search required to examine the *elected* group is co-extensive with the search required to examine groups I-XIII, even though the inventions of groups I-XIV are distinct for the reasons set forth in the preceding Office action mailed September 17, 2002 (Paper No. 5), the criteria required to properly restrict the inventions of groups I-XIV has not been met and accordingly groups I-XIV are rejoined. Otherwise, the restriction requirement is deemed proper, because the inventions are distinct for the reasons set forth in the preceding Office action; therefore, the restriction requirement is made FINAL.

Non-compliance with the Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §

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1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants must comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825) before the application can be further examined under 35 U.S.C. §§ 131 and 132.

As noted on the attached Notice to Comply, the sequence disclosures that must be made compliant appear on page 15, in line 10, and page 17, in lines 14 and 15, of the specification.

Applicants are given the same period of time within which to reply to this Office action to place this application in compliance with the sequence rules set forth under 37 CFR §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Specification

6. The specification is objected to because "Tween™" is misspelled on page 18 in line 8. Appropriate correction is required in reply to this Office action.

7. The specification is objected to because of the use of improperly demarcated trademarks. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

The improper use of the trademark "TWEEN" appears on page 18. Appropriate correction of this deficiency and any other is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

Claim Objections

8. Claims 1-5 and 14-18 are objected to because claims 1 and 14 are drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required in reply to this Office action.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method comprising detecting S100-AG, but the specification does not describe the invention. In fact, the specification does not describe S100-AG, or an antibody that binds specifically to S100-AG.

Searches of numerous textual databases, including MEDLINE and WEST, using "S100-AG" as a query revealed that the term is not apparently known or used in the art.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of

ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

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Because the specification fails to describe a protein designated S100-AG or an antibody that binds such a protein, the specification is deemed insufficient to reasonably convey to the skilled artisan that Applicants had possession of the claimed invention at the time the application was filed. Therefore, this application fails to meet the written description requirement set forth under 35 USC § 112, first paragraph.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,150,345-A.

US Patent No. 6,150,345-A teach a kit or pre-packaged fluorescently-labeled anti-S100 antibody, which is manufactured by DAKO.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,150,345-A in view of Ostergaard, et al (*Cancer Research* 57: 4111-4117, 1997).

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US Patent No. 6,150,345-A ('345) teaches that which is set forth in the rejection under 35 USC § 102(e) above, but '345 does not teach that a kit further comprising a labeled secondary antibody that immunospecifically binds the anti-S100 antibody.

Ostergaard, et al teach an indirect immunofluorescence assay that uses a rhodamine-labeled secondary antibody that binds specifically to the primary antibody.

In view of the teachings of '345 and Ostergaard, et al, it would have been *prima facie* obvious to one of ordinary skill in the art to manufacture a kit comprising an anti-S100 primary antibody and a rhodamine-labeled secondary antibody that binds the primary antibody. One would have been motivated at the time the invention was made to have done so, because such a kit would obviate the need to label the primary antibody directly.

Conclusion

15. No claims are allowed.

16. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Tockman, et al teach considerations in bringing a cancer biomarker to clinical application. Brouard, et al teach urinary secretion of S100A7 in patients with melanoma. Seregni, et al, Guo, et al, and Buer, et al teach S100 levels in the serum of patients with melanoma. Moog-Lutz, et al and Leygue, et al teach expression of S100A7 in breast cancer. Watson, et al review the literature with regard to S100A7. Sherbet, et al review the literature with regard to S100A4. US Patent No. 5,702,920-A teaches a method comprising measuring levels of S100A8 and S100A9. US Patent No. 5,849,528-A teach a method comprising measuring the level of S100P.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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slr

April 3, 2003



ANTHONY C. CAPUTA
CUTTERGY PATENT EXAMINER
TECHNOLOGY CENTER 1600